

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **Kazunori KUSANO**

Art Unit: **3732**

Application Number: **10/527,338**

Examiner: **Sunil K. Singh**

Filed: **March 10, 2005**

Confirmation Number: **3526**

For: **KIT FOR DIAGNOSING PULP EXPOSURE AND A PROBE SYRINGE**

Attorney Docket Number: **082407**

Customer Number: **38834**

**DECLARATION UNDER 37 C.F.R. §1.132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Kazunori KUSANO, a citizen of Japan, hereby declare and state the following:

1. I graduated from Kanagawa Dental University of Yokosuka-shi, Kanagawa-ken, Japan in March 1992 with a degree in dentistry. In May 1992, I acquired a national license to practice dentistry.

2. In April 1992, I joined Shibuya Hospital (now Oral Research Clinic) as a Resident. In January 1994, I opened the Kusano Dental Office Action in Machida-shi, Tokyo-to, Japan, where I serve as Director and Dentist.

3. I have read and am familiar with the above-identified patent application as well as the Official Action dated November 17, 2009, in the application.

4. I have read and am familiar with the contents of cited references, U.S. Patent Nos. 6,508,647 to Kusunori KUSANO; and 4,105,715 to Edward Roger GLEAVE cited in the Official Action in the above-identified application.

5. Based on my knowledge and experience, I provide the following comments about cyanoacrylates such as 2-cyanoacrylate generally. Cyanoacrylate polymerizes when it comes into contact with water. 2-cyanoacrylate (2-cyanoacrylic acid ester), the chief component of the adhesive of Gleave, includes a vinyl group ( $-\text{CH}_2=\text{C}-$ ) and two strong electron attracting groups, a cyano group ( $-\text{C}\equiv\text{N}$ ) and a carbonyl group ( $>\text{C}=\text{O}$ ). Furthermore, 2-cyanoacrylate cures by anionic polymerization. Specifically, a negative ion (anion) is provided by a compound such as water ( $\text{H}_2\text{O}$ ), methanol ( $\text{CH}_3\text{OH}$ ), or sodium hydroxide ( $\text{NaOH}$ ). In the molecular structure of these, the  $\text{OH}^-$  group reacts with cyanoacrylate, causing polymerization/curing. Typically, this can even occur with just the  $\text{OH}^-$  group of the small amount of water contained in the air.

6. Based on my knowledge and experience, I provide the following comments about the applicability of cyanoacrylates such as 2-cyanoacrylate to dentistry, and root canals in particular. The chief component of a cyanoacrylate paste will cure/polymerize in the presence of  $\text{OH}^-$  from water, for example. The oral cavity is moister than the outside of the body and becomes moister with respiration. As such, the cyanoacrylate adhesive paste of Gleave will cure/polymerize quickly due to the moisture in the air or in a patient's oral cavity, and will not reach the target location. Furthermore, even if the cyanoacrylate reaches the target position, it will cure instantly when it reaches the target position. This is because there is blood/lymph fluid in the dental pulp or blood/effusion in the apical area/periodontal membrane area, and these add more moisture than the moisture which is already present in the oral cavity and air. Please see "The Practice of Root Canal Fixative Methods Using Calcium Hydroxide" by Yuichi Kimura et al., Foundation – Oral Health Association of Japan, attached. Also, a cyanoacrylate adhesive

paste would harden after reaching the dental pulp from the carious cavity, the dental pulp/periodontal membrane area from a fracture line, or the apical area through the root canal. As such, the paste would harden to the point that it is impossible to clean it away. As such, a cyanoacrylate paste is problematic for this type of dental application.

7. Based on the above, I have concluded, among other things, that it would not have been obvious to modify U.S. Patent No. 6,508,647 by utilizing the cyanoacrylate adhesive paste of Gleave, at least because the paste of Gleave would be disadvantageous in the context of U.S. Patent No. 6,508,647.

The undersigned declares that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

  
Dr. Kazumori KUSANO

Signed this 11 day of May, 2010.